The information contained in this amendment to the reclassification petition for metal/metal semi-constrained hip joint prostheses is in response to a request by FDA for additional information concerning these devices. The request by FDA was made during a November 13, 2000 teleconference between the members of the Orthopaedic Surgical Manufacturers Association (OSMA) reclassification petition task force and the Agency. The items from that teleconference have been summarized and are followed by the responses from OSMA.

Item 1

The proposed CFR classification definition appearing in Section III, pp. 15-16 of the original petition does not address all types of pre-amendments and post-amendments metal/metal semi-constrained hip prostheses. The definition should be revised to include uncemented, non-porous coated hip prostheses, e.g., hip prostheses with acetabular components fixed by means of circumferential threads on the cup perimeter or acetabular components fixed by means of spikes or threaded screws. Any proposed reclassification of these devices should include recommendations of performance standards or other special controls that could be implemented to control for the risks known to be associated with these devices.

Response

The revised proposed definitions and proposed regulatory classifications which include the information described above is provided as Exhibit 1 of this amendment.

Item 2

Pages 46-77 in Section VII- B. Published Reports describe a summation of several significant reports found in the published literature. Provide the criteria for selection of those articles appearing in the literature summary.

Response

The articles selected for use in Section VII- B. Published Reports of the reclassification petition were chosen based on their relevance to the risks identified in Section IX.- Regulatory Control Of Risks on pages 87-93. Specifically, these topics included historical perspectives on the development and evolution of metal-on-metal hip prostheses, clinical experience in the use of these devices, and research related issues, e.g., physiologic and biologic issues. Published articles were identified using literature searches on various computerized medical databases. Pertinent articles that were identified were included in the summary and in the bibliography of Appendix 2, pages 211-229.

Item 3

Provide a rationale that justifies the pooling of the clinical and radiographic data presented from the four multicenter clinical investigations reported in pages 34-45 of Section VII- A. Unpublished Clinical Studies and in pages 148-210 of Appendix 1. Alternatively, you may choose to present the stratified data from each multicenter

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study and should include a description of the device configuration(s), as well as descriptions of the study protocol and population treated in each study.

Response

The stratified data from the four multicenter studies including device descriptions, patient demographics and study designs are provided in Exhibit 2 and in Appendices 1,2.

Other Information

Table 7 of Section VII- Published/Unpublished Clinical Results on page 45 of the original reclassification petition contained errors for three of the reported postoperative systemic complications. A revised table 7 with the corrected data highlighted is included as Appendix 3 of this amendment.

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